

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| In re Application of: Tarara et al. | Group Art Unit: 1611 |
| Application No: 09/886,296 | Examiner: Welter, Rachael E. |
| Confirmation No: 6348 | |
| Filing Date: June 21, 2001 | Attorney Docket No: 53250-US-CNT[3] (NV.0054.10) |
| For: ENGINEERED PARTICLES AND METHODS OF USE | June 7, 2010 San Francisco, California 94107 |

REPLY BRIEF

VIA ELECTRONIC FILING

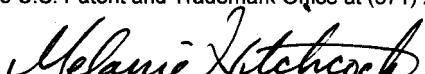
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Examiner:

In response to the Examiner's Answer mailed on April 28, 2010, the Applicant of the above-referenced patent application (hereinafter Appellant) hereby maintains the appeal to the Board of Patent Appeals and Interferences. Appellant requests the reversal of the Final Rejection.

Certificate of Transmission

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By: 
Melanie Hitchcock

Date: June 7, 2010

Status of Claims

Claims 57, 59-80 and 82-102 are presently pending in the case. Claims 57, 59-80 and 82-102 have been finally rejected. The rejection of each of claims 57, 59-80 and 82-102 is hereby appealed.

Claims 1-56, 58 and 81 have been cancelled.

Grounds of Rejection to be Reviewed on Appeal

Appellant continues to request review of the Examiner's following grounds of rejection:

Claims 57, 59-80 and 82-102 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Appellant regards as the invention.

Claims 57, 59-77, 80 and 82-100 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Hanes et al in view of a 1975 journal article to Papahadjopoulos et al (hereinafter Papahadjopoulos et al), as evidenced by Mori et al.

Claims 78 and 101 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Hanes et al in view of Mathiowitz et al or Cohen et al or Papahadjopoulos et al, as evidenced by Mori et al, and further in view of Igarashi et al.

Claims 79 and 102 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Hanes et al in view of Mathiowitz et al or Cohen et al or Papahadjopoulos et al, as evidenced by Mori et al, and further in view of Benson et al.

Claims 57, 59-80 and 82-102 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 8, 9, 11-15, 17, 19-25, 29-32, 53-55, 57-62 and 64-89 of U.S. Patent Application No. 09/851,226 (now US Patent 7,442,388).

Claims 57, 59-80 and 82-102 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6, 7, 9, 10, 46-50, 54-57, 59, 61-67, 69, 70, 74-77 and 79-90 of U.S. Patent Application No. 09/568,818.

Claims 57, 59-80 and 82-102 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15, 19-22, 37-49, 52-64, 67-79, 82, 83, 94 and 102 of U.S. Patent Application No. 10/750,934.

Claims 57, 59-80 and 82-102 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 and 32-39 of U.S. Patent Application No. 10/982,191.

The following rejections were argued in the Appeal Brief but were withdrawn by the Examiner in the Examiner's Answer:

Claims 57, 59-77, 80 and 82-100 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 5,855,913 to Hanes et al (hereinafter Hanes et al) in view of U.S. Patent 6,120,751 to Unger (hereinafter Unger) as evidenced by U.S. Patent 5,776,488 to Mori et al (hereinafter Mori et al).

Claims 78 and 101 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Hanes et al in view of Unger and as evidence by Mori et al, and further in view of U.S. Patent 4,201,774 to Igarashi et al (hereinafter Igarashi et al).

Claims 79 and 102 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Hanes et al in view of Unger and as evidence by Mori et al, and further in view of U.S. Patent 5,006,343 to Benson et al (hereinafter Benson et al).

Claims 57, 59-77, 80 and 82-100 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Hanes et al in view of U.S. Patent 6,248,720 to Mathiowitz et al (hereinafter Mathiowitz et al) or U.S. Patent 5,149,543 to Cohen et al (hereinafter Cohen et al), as evidenced by Mori et al.

Argument

Appellant believes each of claims 57, 59-80 and 82-102 is improperly rejected and is therefore allowable for the reasons set forth in Appellant's Appeal Brief filed on January 22, 2010. The present Reply Brief is being filed to specifically address some of the issues raised by the Examiner in the Examiner's Answer mailed on April 28, 2010. The comments herein are merely supplemental to the arguments made in the Appeal Brief and are not meant to replace those arguments.

35 USC 103(a) rejections based on Hanes et al, Unger and Mori et al

The Examiner's rejection of independent claim 57 under 35 USC §103(a) as being unpatentable over Hanes et al in view of Unger as evidenced by Mori et al was withdrawn by the Examiner. Appellant acknowledges the withdrawal with appreciation.

35 USC 103(a) rejections based on Hanes et al, Mathiowitz et al, Cohen et al and Mori et al

The Examiner's rejection of independent claim 57 under 35 USC §103(a) as being unpatentable over Hanes et al in view of Mathiowitz et al or Cohen et al, as evidenced by Mori et al, was withdrawn. Appellant acknowledges the withdrawal with appreciation.

35 USC 103(a) rejections based on Hanes et al, Papahadjopoulos and Mori et al

The Examiner's rejection of independent claim 57 under 35 USC §103(a) as being unpatentable over Hanes et al in view of Papahadjopoulos et al, as evidenced by Mori et al, was not withdrawn. The rejection continues to be improper and should be reversed.

Hanes et al, Papahadjopoulos et al and Mori et al do not render independent claim 57 unpatentable. Claim 57 is to an inhaleable powder composition comprising a plurality of particulate microstructures, the particulate microstructures comprising, *inter alia*, a structural matrix comprising phospholipid and calcium, wherein the particulate microstructures comprise greater than about 50% phospholipid. Hanes et al does not teach an inhaleable powder as claimed, and Papahadjopoulos et al and Mori et al fail to make up for the deficiencies of Hanes et al, as will be explained.

Hanes et al does not disclose or suggest a particulate microstructure comprising greater than about 50% phospholipid. Instead, Hanes et al discloses two different versions of particles. The first version is directed to particles that are primarily composed of polymer (see abstract lines 7-10 and columns 5 and 6). While this version may include small amounts of surfactant, nowhere is it disclosed that greater than about 50% of the particle is phospholipid. In all of the exemplified versions, the bulk of the particle is polymer. Thus, the particulate microstructures of claim 57 are not disclosed in the first version of Hanes et al particles.

The second version is mentioned but not exemplified in Hanes et al. In this second version, Hanes et al mentions that the particles “may be formed solely of the drug or diagnostic agent and a surfactant.” This second version, too, fails to meet the claim language. Appellant’s claim 57 requires calcium in addition to phospholipid. Therefore, Hanes et al particles that are made up **solely** of drug and surfactant would not render the particles of claim 57 unpatentable.

The teachings of Papahadjopoulos et al and Mori et al do not make up for the deficiencies of Hanes et al. Claim 57 recites the presence of phospholipid and calcium, and one of ordinary skill in the art would not have been motivated to combine Hanes et al and Papahadjopoulos et al in a manner that would arrive at the invention of claim 57.

Concerning the first version of Hanes et al (*i.e.*, the polymer, phospholipid, drug version), Hanes et al teaches primarily polymeric particles, as discussed above.

Papahadjopoulos et al is relied upon to teach the desirability of adding calcium for calcium-polymer interactions. However, even if one were to combine the teachings of Papahadjopoulos et al with the primarily polymeric particles of Hanes et al, one would not arrive at particles that are greater than 50% phospholipid, as required by claim 57.

Concerning the second version of particles disclosed by Hanes et al (*i.e.*, particles that are solely surfactant and drug), one of ordinary skill in the art would not have combined the teachings as proposed by the Examiner. First, Hanes et al teaches away from additional components by its use of “solely.” Secondly, if there is no polymer in the particle, the calcium-polymer interactions discussed by Papahadjopoulos et al would not apply. Accordingly, Papahadjopoulos et al is not properly combinable with either particle version taught by Hanes et al in a manner where one of ordinary skill in the art would arrive at Appellant’s invention as set forth in claim 57.

The Examiner’s comments in the Examiner’s Answer do not serve to show that claim 57 is unpatentable based on Hanes et al and Papahadjopoulos et al. On page 21 of the Examiner’s Answer, the Examiner states that “an ordinary skilled artisan would envisage and be able to make particulates comprising more than 50% phospholipid...” Appellant contends the “would be able to” standard applied by the Examiner is improper and without basis.

Mori et al is not relied upon to make up for the deficiencies of Hanes et al and Papahadjopoulos et al, nor does it.

Appellant continues to requests reversal of the rejection of claim 57 under 35 U.S.C. §103(a).

The balance of the claims is allowable for the reasons set forth in the Appeal Brief.

Conclusion

Thus, it is believed that all rejections made by the Examiner have been addressed and overcome by the above arguments and the arguments provided in the Appeal Brief. Therefore, all pending claims are allowable. A reversal is respectfully requested.

Should there be any questions, Appellant's representative may be reached at the number listed below.

Respectfully submitted,

JANAH & ASSOCIATES

Dated: June 7, 2010

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